

The National Academy of Medicine Report on Diagnostic Errors: Implications for Laboratory Practice

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**I have no conflicts
of interest.**

**This presentation is a
summary of the Institute of
Medicine Committee on
Diagnostic Error
AND**

**It is my personal summary of the
number of errors experienced by
Americans today**

Methods of the Study

The Committee deliberated during five in-person meetings and numerous conference calls between April 2014 and April 2015. At three of the meetings, the Committee invited a number of speakers to inform its deliberations.

Origin of Task and Committee Charge

The IOM appointed an independent committee with a broad range of expertise, including:

Diagnostic error, patient safety, health care quality and measurement, patient engagement, health policy, health care professional education, cognitive psychology, health disparities, human factors and ergonomics, health information technology (health IT), decision analysis, nursing, radiology, pathology, law, and health economics.

Outline of the Presentation

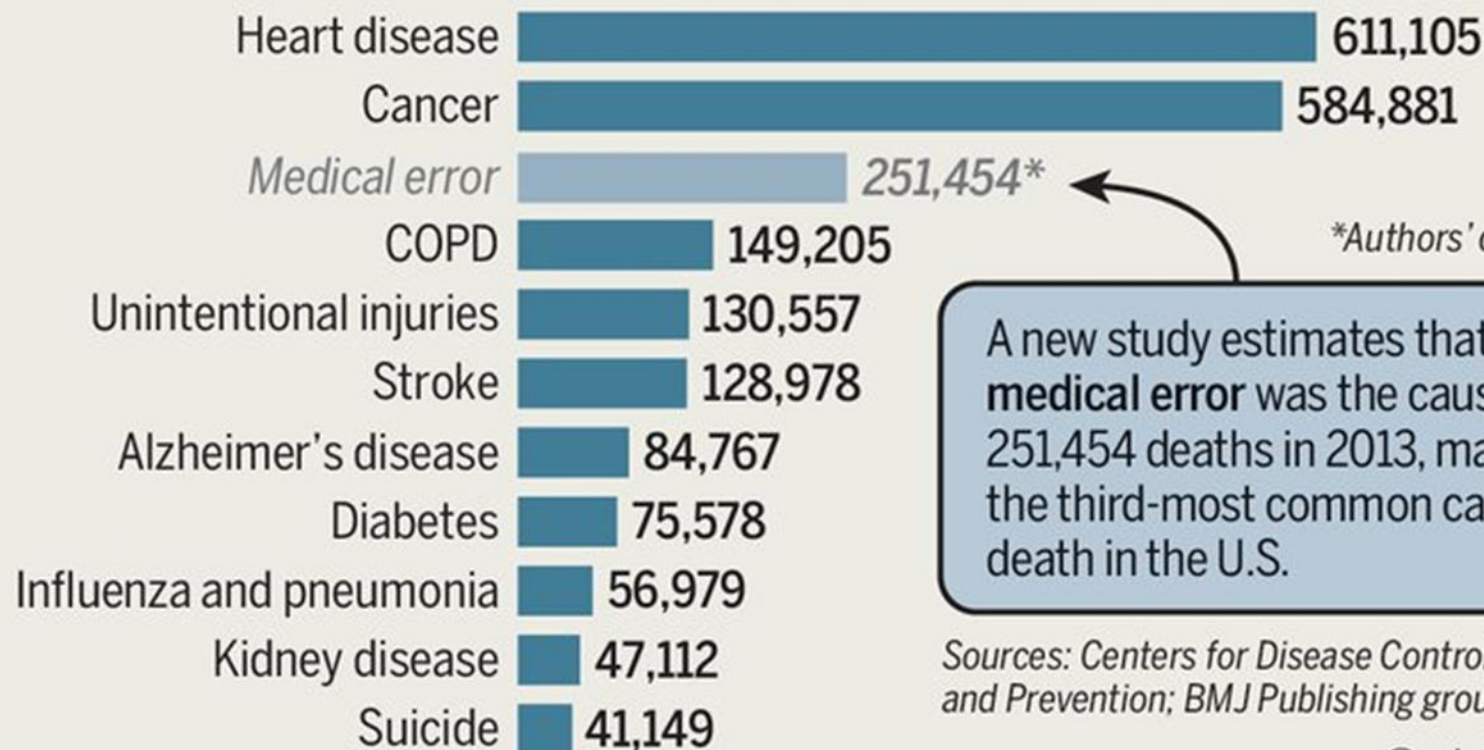
1. **Medical error**
2. Diagnostic error
3. Why medical errors have been overlooked
4. What is broken and what are the fixes
5. The percentage of Americans experiencing diagnostic error
6. Perspectives

Medical Error

**Includes All Medical
Mistakes:
Treatment and Diagnostic**

■ Top ten causes of death, 2013

■ *Estimate*



*Authors' calculation

A new study estimates that **medical error** was the cause of 251,454 deaths in 2013, making it the third-most common cause of death in the U.S.

Sources: Centers for Disease Control and Prevention; BMJ Publishing group Ltd.

@sdutgraphics

ICD-10 Coding System Cannot Capture Medical Errors

Myocardial infarction	X
Stroke	X
Cancer	X
Diabetes	X

**No code for an ADMISSION or READMISSION
following a missed or delayed diagnosis!**

There have been at least three studies providing estimates of the number of deaths associated with medical error:

**80,000 to 160,000 per year
*BMJ Qual Saf 22:672, 2013***

**400,000 per year
*J Patient Saf 9:122-128, 2013***

**251,000 per year in 2013
*BMJ 353:i2139, 2016***

**Taking an average of these, there are
257,000 deaths per year
contributed to medical error with
25 percent
as diagnostic error-related deaths**

**There are an estimated
64,000 deaths annually
due to diagnostic error**

Wars Ranked by US Combat Deaths

Rank	War	Years	Deaths
1	World War II	1941–1945	291,557
2	American Civil War	1861–1865	212,938
3	World War I	1917–1918	53,402
4	Vietnam War	1955–1975	47,424
5	Korean War	1950–1953	33,746
6	American Revolutionary War	1775–1783	8,000
7	War on Terror	2001–present	5,281
8	War of 1812	1812–1815	2,260
9	Mexican-American War	1846–1848	1,733
10	Northwest Indian War	1785–1795	1,221+
11	Kosovo	1999-2014	18+

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Diagnostic Error

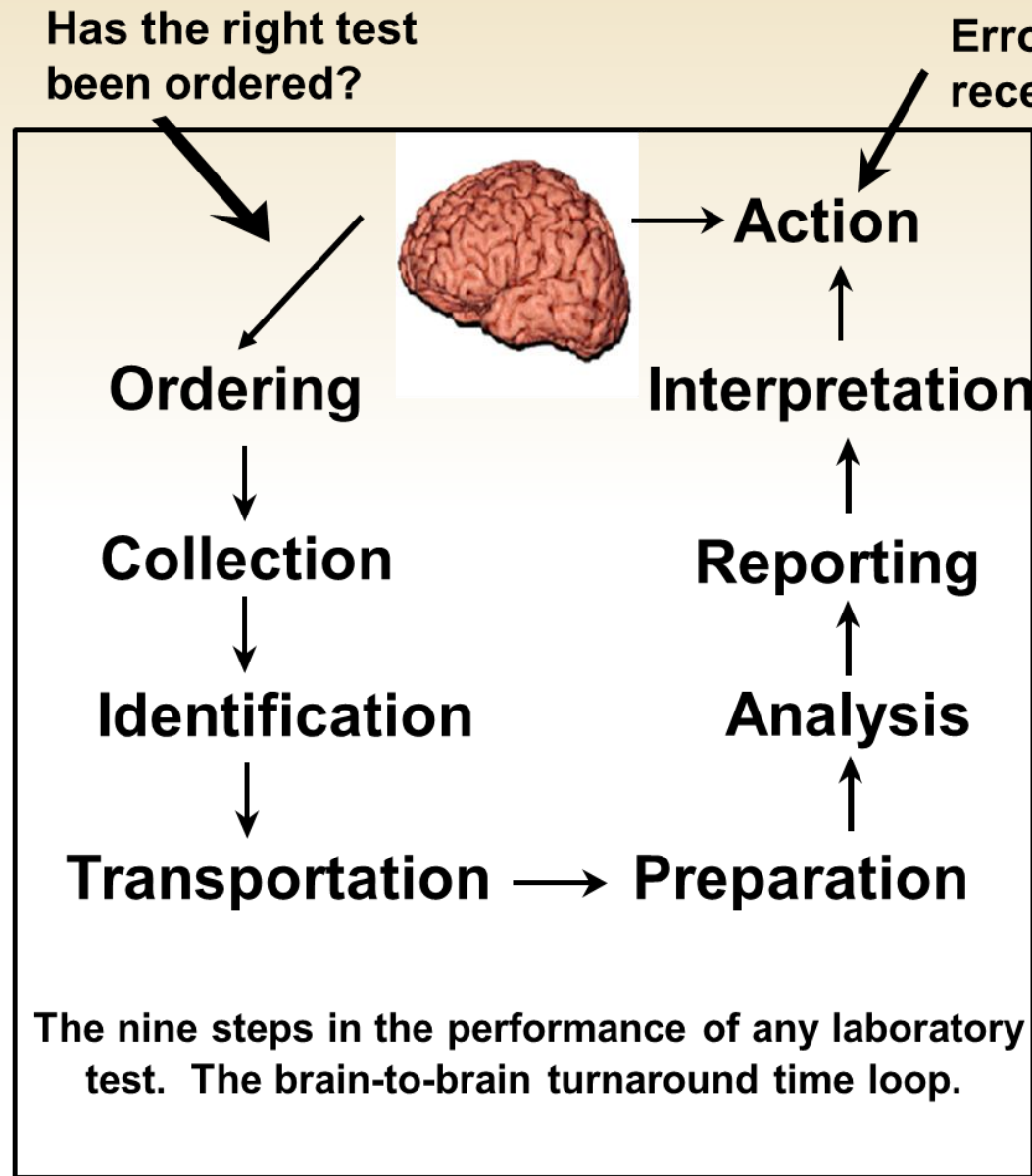
A Subset of Medical Errors

Conceptual Model

The Committee developed a patient-centered definition of diagnostic error:

The failure to (a) establish an accurate and timely explanation of the patient's health problem(s) or (b) communicate that explanation to the patient.

Diagnostic Error: An error that occurs in any one of the steps shown in this diagram



The Most Common Misdiagnoses Involve Frequently Encountered Disorders – and These Misdiagnoses Can Occur from Underutilization of Lab Tests

Adults: Lung Cancer

Acute MI

Colorectal Cancer

**Pulmonary
Embolism**

Acute Stroke

Children: Meningitis

Pneumonia

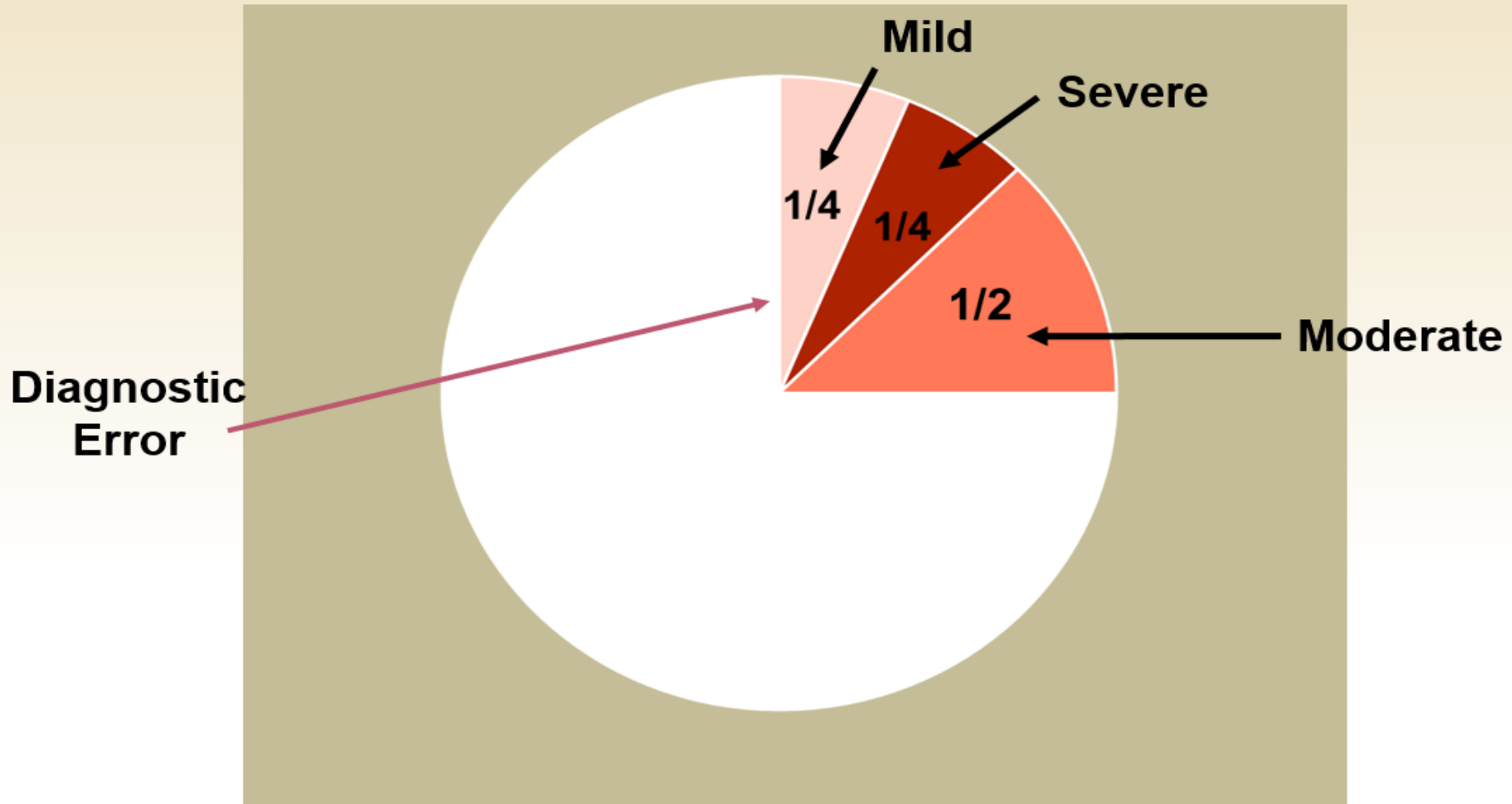
Malignant Tumor

Benign Tumor

Appendicitis

<https://www.thedoctors.com/the-doctors-advocate/third-quarter-2014/diagnostic-error-in-medical-practice-by-specialty/>

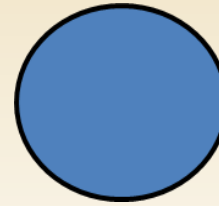
Diagnostic Error as Percentage of Medical Error



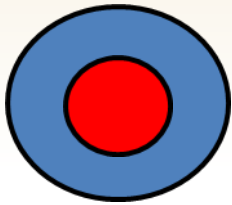
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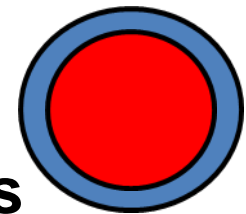
1950



**Amount of
knowledge available
about disease**

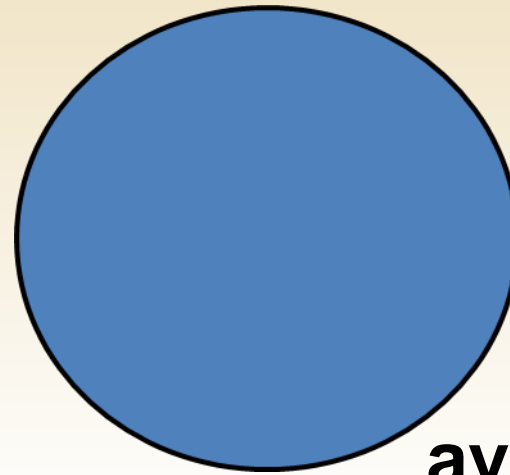


**Doctor does
not know much
about diagnosis**



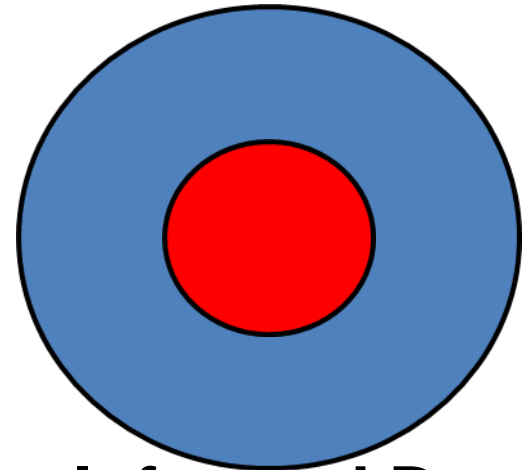
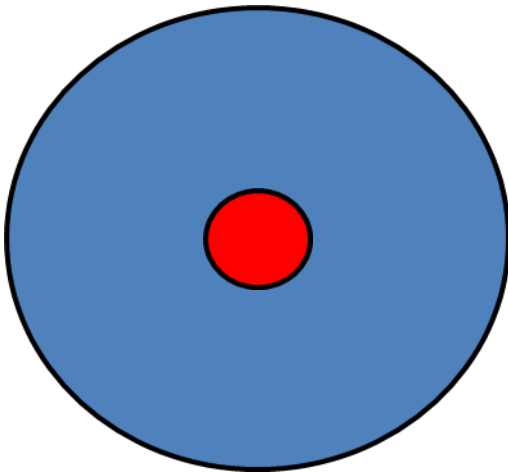
**Doctor knows
much about diagnosis**

Today



**Amount of
knowledge
available about
disease**

Less Informed Doctor



More Informed Doctor

The Complication from a Diagnostic Error May Appear Months-to-Years After the Mistake Has Been Made

During the period of 1981 to 1984:

- An ear, nose, and throat surgeon is faced with an eight year old boy requiring a tonsillectomy**
- The boy has a PTT that is elevated**
- Without knowing that the boy has a deficiency in a coagulation factor (XII) that is not predisposed to bleeding, the surgeon orders fresh frozen plasma**
- One out of 20 bags of fresh frozen plasma contains active hepatitis C virus or HIV**

The Complication from a Diagnostic Error May Appear Months-to-Years After the Mistake Has Been Made

What is the likelihood that the ENT surgeon's diagnostic error years earlier regarding the prolonged PTT is perceived as the cause of these dreaded infections?

This is highly unlikely to be counted as a diagnostic error

The Most Dangerous Scenario of All:

**When Doctors “Don’t Know What
They Don’t Know”**

***But They Actually Think
They Do Know It***

Not Knowing What You Do Not Know as a Physician is the Biggest Problem

Patient is 22 years old and claims to be pregnant because she has missed a period. She presents with abdominal pain and needs an imaging study.

The imaging study should not be performed if the patient is pregnant as the radiation can be harmful to a fetus.

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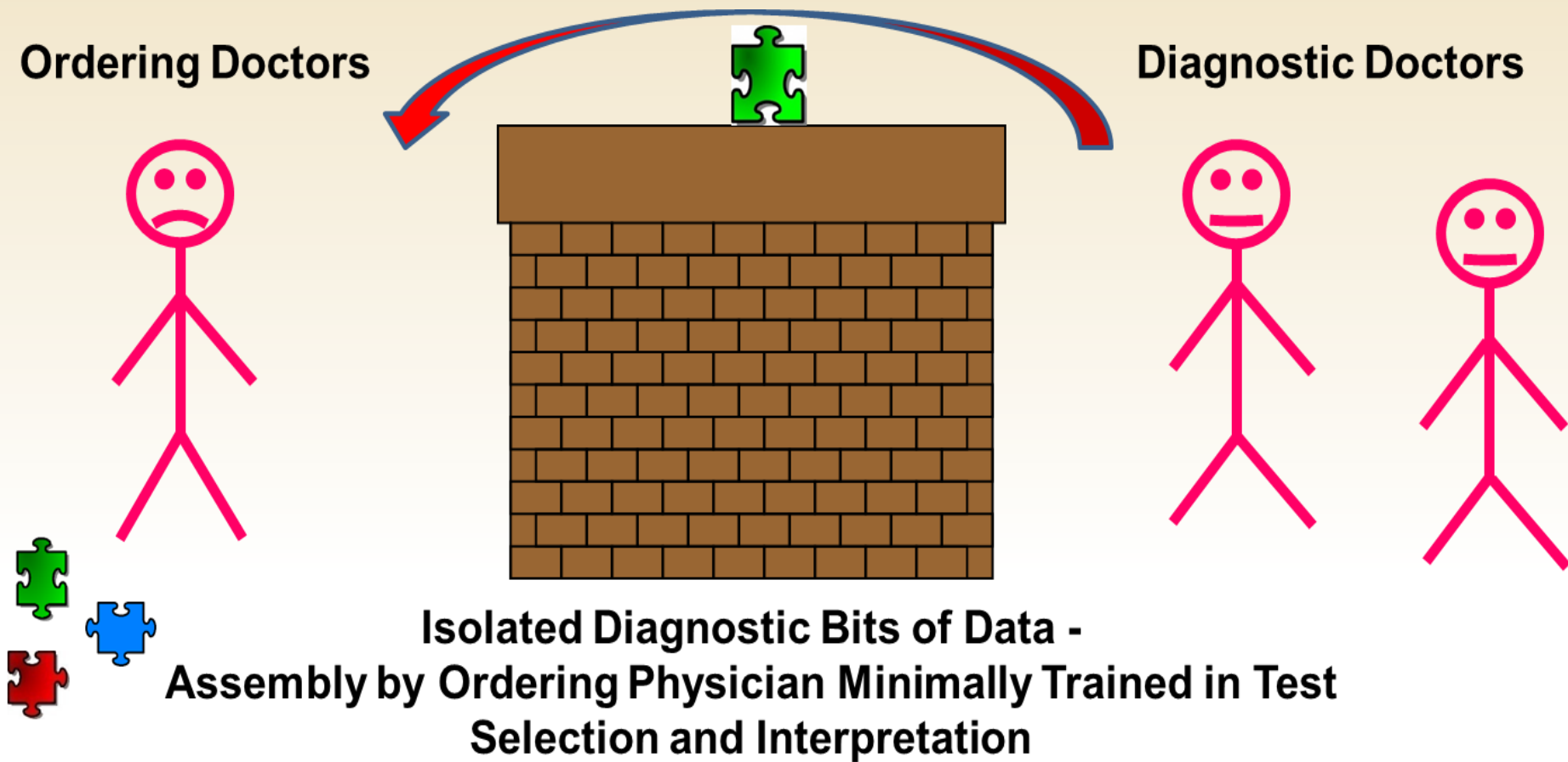
What is Broken and What Can be Done to Fix It

What is Broken?

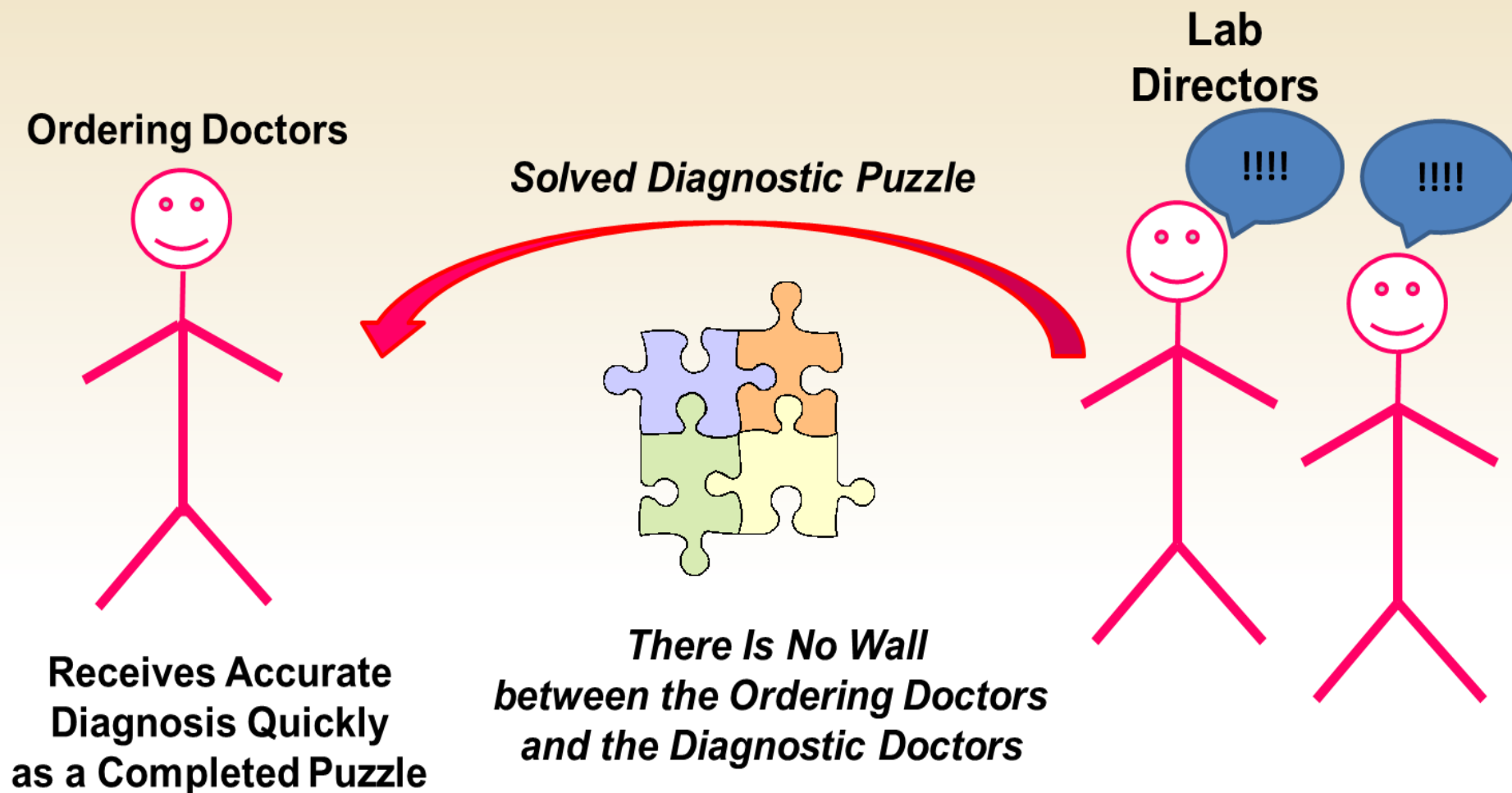
**Failure to build
diagnostic teams
of health professionals**

The Diagnostic Management Team Provides Advice on the Appropriate Laboratory Tests to Select and the Interpretation of Complex Clinical Laboratory Evaluations

Conventional Approach



Diagnostic Management Team Approach



Data Presentation in the Medical Record for Coagulation Studies Prior to Initiation of the Patient-specific, Expert-driven Coagulation Interpretation

June 30, 2010

**Pat-PT: 13.9 PT-inr: 1.1 PTT-pt:
43.6* PoolINP: 28.1 P+N0Hr:
38.3 P+N1Hr: 36.2 P+N2Hr:
35.9 Pat-TT: 15 F8Act:
95 F9Act: 102 RVVT:
1.5* DRVVT: Lupus
Anticoagulant Confirmed DMX:
1.3 F11Act: 96 F12Act: 54**

Report in the Medical Record After Initiation of the Daily Rounds to Interpret All Complex Evaluations from the Special Coagulation Laboratory

July 1, 2010

This patient has an elevated PTT, with a normal PT/INR and normal thrombin time.

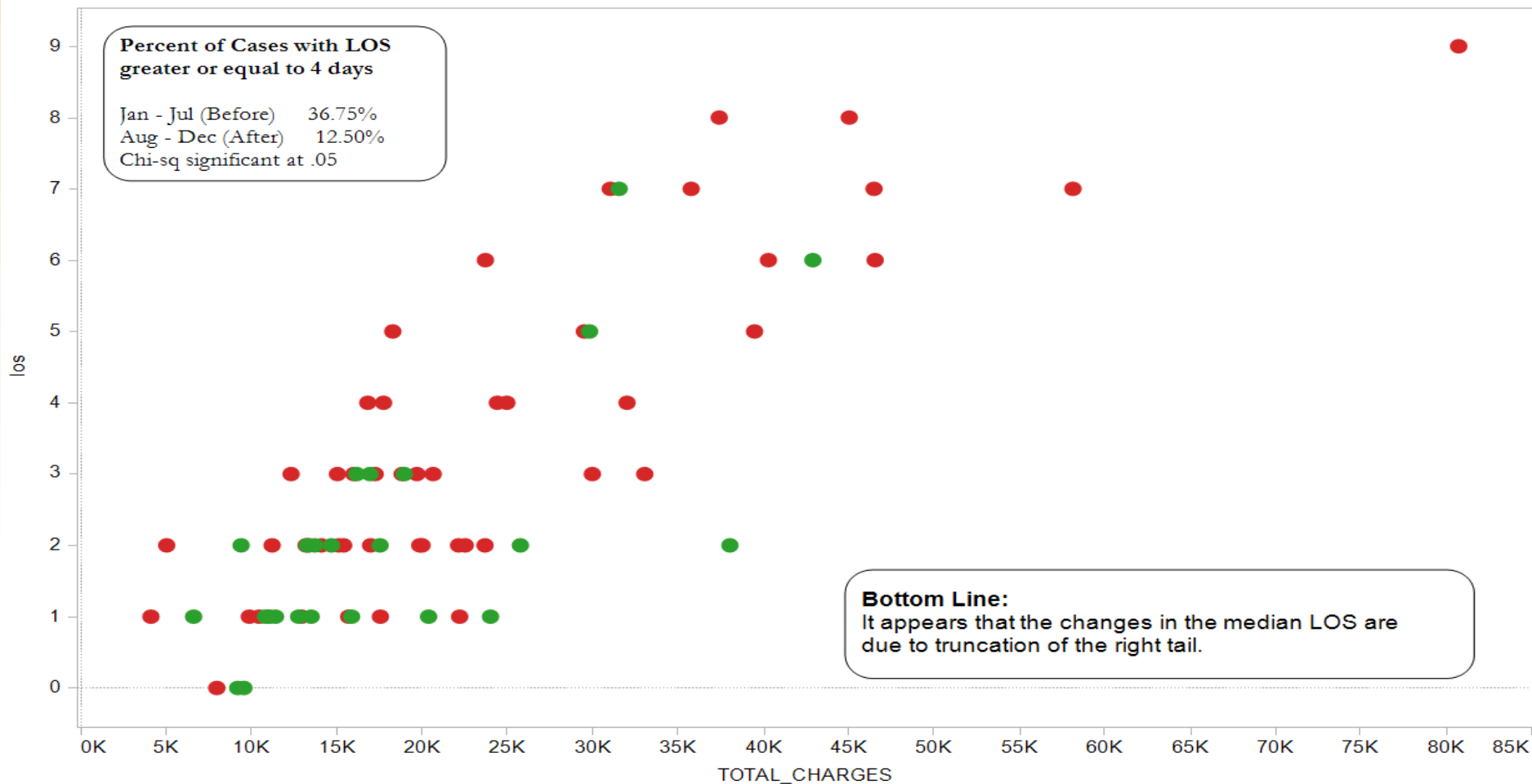
A PTT mixing study failed to correct into the normal range. These results were consistent with the presence of an inhibitor (such as a lupus anticoagulant) in the sample.

The Dilute Russell Viper Venom time (dRVVT) is used for detection of Lupus Anticoagulant, and the test was positive, indicating the presence of Lupus Anticoagulant.

Taken together, this is a patient with a prolonged PTT based upon the presence of a lupus anticoagulant. There is no increased bleeding risk in this patient, despite the prolonged PTT.

MSDRG 176: PE

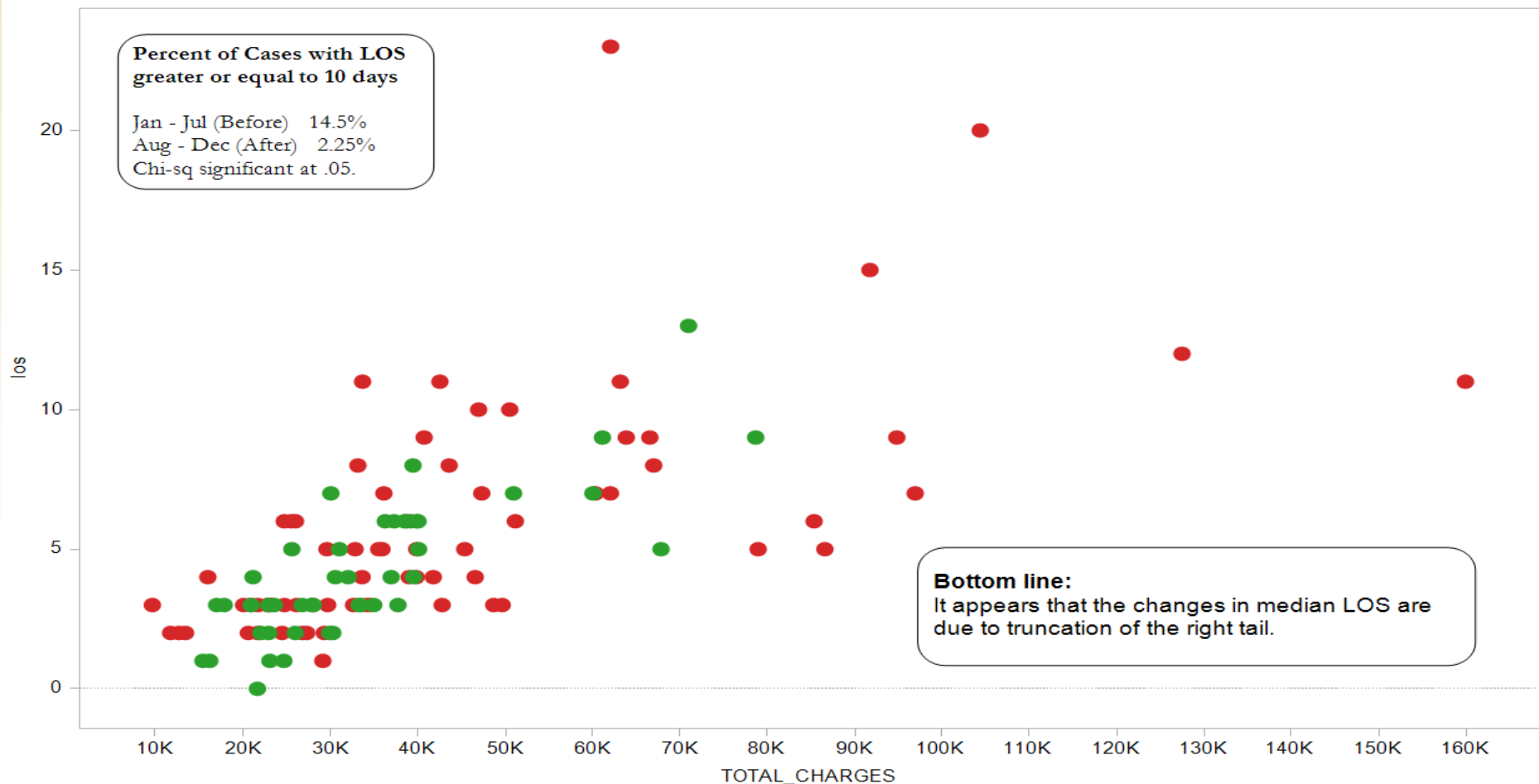
Comparison of Length of Stay and Total Charges Pre and Post Aug 1, 2010



Aquino, AC. How to spot the savings from a diagnostic team. CAP Today, October 2017

MSDRG 65: Intracranial Hemorrhage

Comparison of Length of Stay and Total Charges Pre and Post Aug 1, 2010



Aquino, AC. How to spot the savings from a diagnostic team. CAP Today, October 2017

The Fix

**Remove the barriers to the
creation of diagnostic
management teams and
pay for the interpretation of
laboratory test results similar to
payment for anatomic pathology
and radiology**

What is Broken?

Failure to involve the patient

**The visits are too short –
most doctors do not have time to clearly
explain to patients what they have and what
to do if they do not recover**

**And many doctors do not have enough
information to explain what the patient
actually has – factor V Leiden?**

The Fix

A new system needs to be put into place that allows more time for discussion between the patient and the physician -

And the willingness of the physician, when necessary, to have an expert describe a patient's condition

What is Broken?

**Failure to optimize health
information technology**

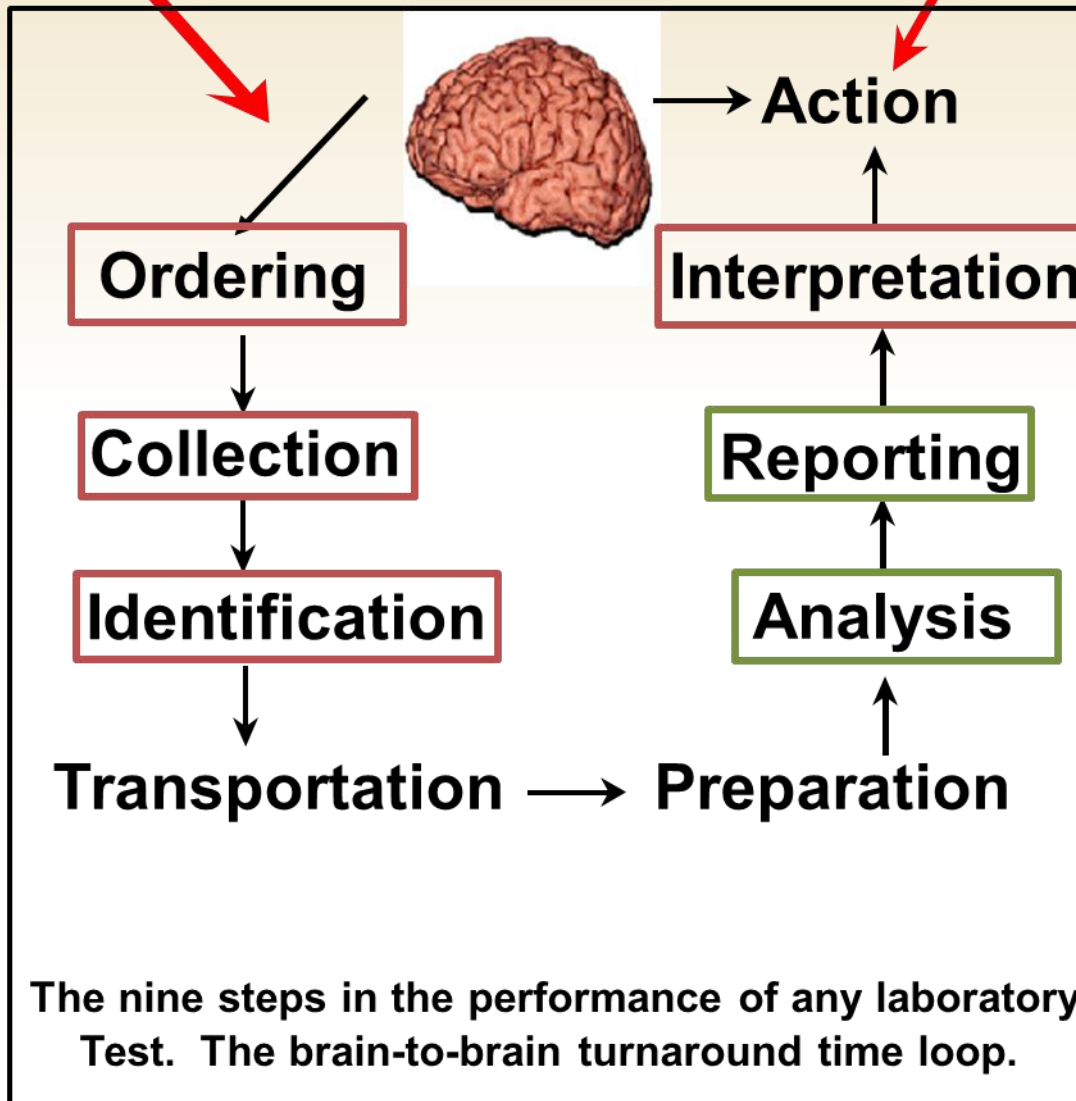
**There is so much more to do than what
we are currently doing that would
significantly benefit patient outcome
and
healthcare expenditures**

Has the right test
been ordered?

Error between result
receipt and action?

A lab system
addresses what
is circled in
green.

To make a major
reduction in
medical error, it
must also
address what
is circled in red.



Am J Clin Pathol 136:829, 2011

The Fix

For the information systems company with adequate resources and a vision for the future –

The principle need is to bring an expert to every healthcare provider who needs help in diagnostic test selection and result interpretation

What is Broken?

Failure to provide payment for individuals in the healthcare system providing advice on the selection and result interpretation for diagnostic tests

The Fix

Pay pathologists and clinical laboratory scientists not only for anatomic pathology services but also for consultation on laboratory test selection and result interpretation,

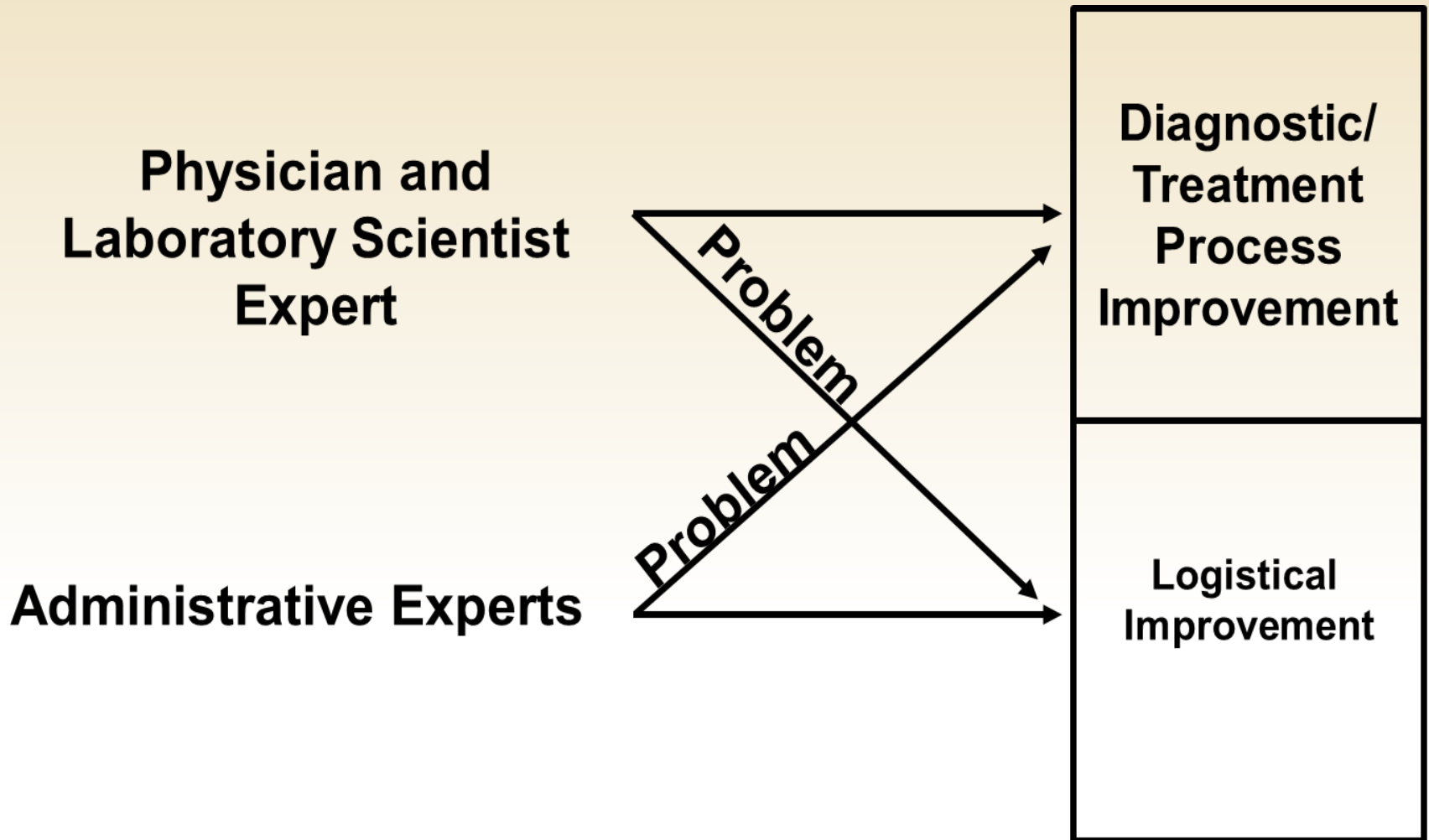
and incentivize them to build expert diagnostic management teams, particularly in academic medical centers where a larger number of pathologists are employed

What is Broken?

**Failure to recognize the impact of
diagnostic error, both immediate
and long-term by**

**Physician and
non-physician healthcare
institution leaders**

Improvement in Clinical Services: Who is the Expert Who Leads the Improvement? What is the Role of the Non-expert?



The Fix

Build a strong partnership between administrators with financial and operational expertise and medical doctors to make decisions with the most information possible –

So cost savings alone are not the driving force and inefficient clinical practices do not prevail

What is Broken?

**Within the health system,
failure to share information
on diagnostic errors between
patients and families due to
legal barriers**

Why Doctors Do Not Want to Tell a Patient About Diagnostic Errors and Imply that Their Own Errors were Caused by Someone Else

- **It is embarrassing**
- **It induces a lack of confidence in the doctor**
- **It may lead to legal action by the patient against the doctor**

Why Doctors Do Not Want to Tell a Patient About Diagnostic Errors and Imply that Their Own Errors were Caused by Someone Else

- It may lead to a reduction of patients in a practice and loss of income**
- Blame is easily passed on to persons/ services not present in the room (“The lab did not do the correct tests” is really “I didn’t know which tests to order and selected the wrong ones”)**

The Fix

Doctors must avoid all misrepresentation about medical errors, large and small –

There must be a willingness to admit that a diagnostic evaluation was incomplete, or overdone, and that a misdiagnosis was not someone else's fault

What is Broken?

Failure to educate medical students on appropriate use of diagnostic tests and when to refer test selection and result interpretation to an expert

Survey of US Medical Schools

Brian Smith and the CLIHC™ Group at the CDC

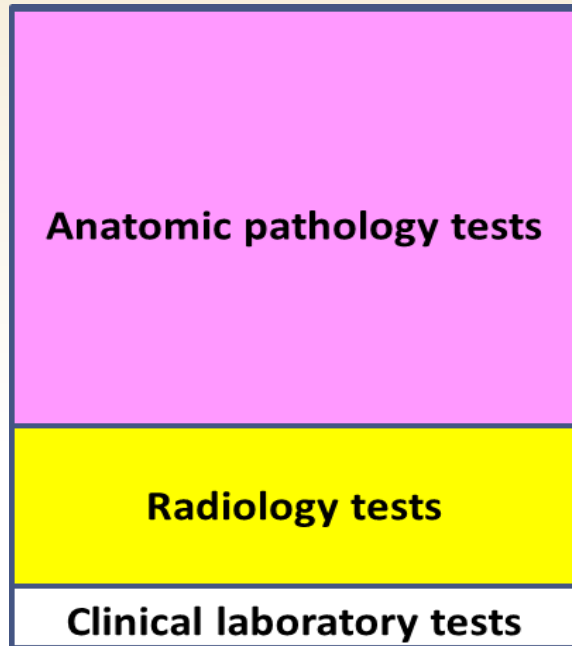
Number of hours spent by medical students learning anatomic pathology: 61 – 302 is the range

Median number of hours spent by medical students learning laboratory medicine: 8 hours of lecture

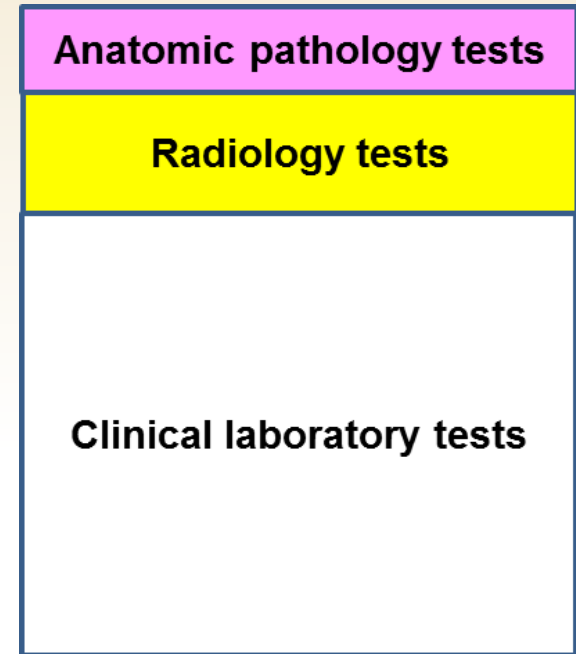
And there is most often no test for the laboratory medicine coursework, and the teaching is often done by individuals with no laboratory medicine training

An Educational Mismatch with Medical Practice Competency Which has Long Needed Correction

What medical students are taught about the diagnostic tests they will use in practice?



What diagnostic tests do doctors order in practice and are required to interpret the test results by themselves?



The Fix

A required course for medical students in the United States to teach the appropriate selection of diagnostic tests and interpretation of test results must be initiated

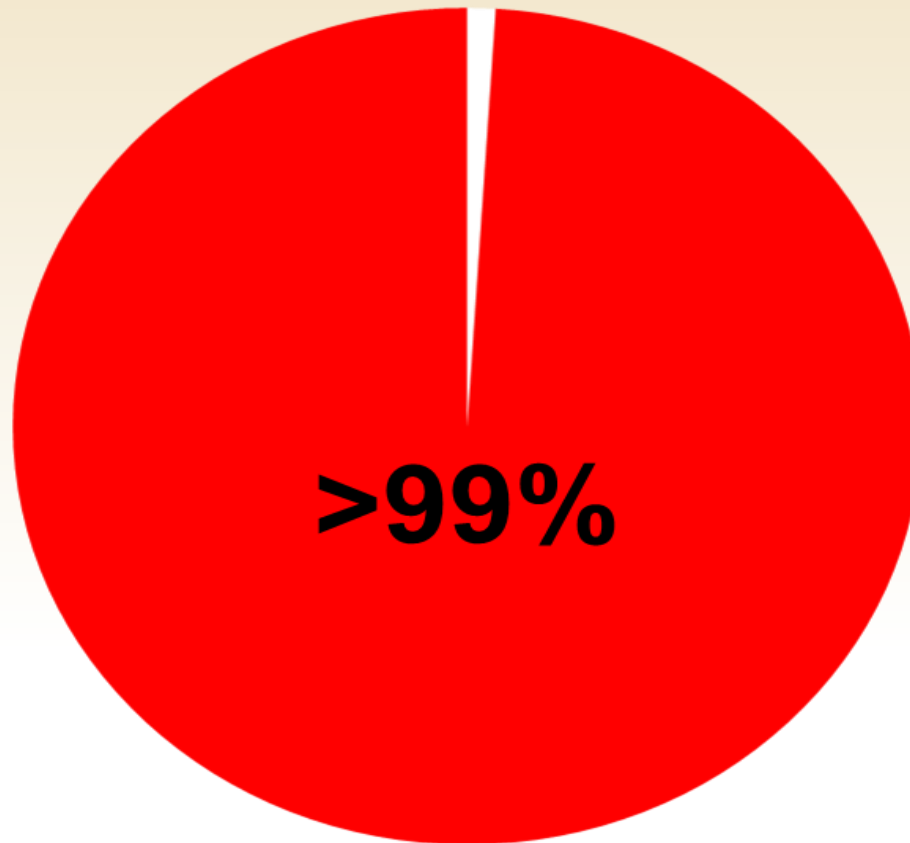
There must be an appropriate number of questions on the licensing board exam on this topic

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The Percentage of Americans Experiencing Diagnostic Error

Percentage of Adult Americans Experiencing Diagnostic Error



How Big is the Problem of Diagnostic Error?

**Post-IOM Report, 2015:
Most adult Americans have experienced
a diagnostic error**

**Today - This Presentation
Personal Data Review:
How many diagnostic errors
per person in a lifetime?
1? 10? 50?**

The Average of the Results for These Six Disease-based Diagnostic Errors

55% Pulmonary embolism

30% Subarachnoid hemorrhage

44% Cancer

21% Breast cancer

69% Bipolar disease

18% Diabetes

An average of 39.5% diagnostic error for the six disease-based examples

Diagnostic Errors Associated with Office Visits and Initial In-patient Visits

Study A
(a summary of six
studies involving six
different disorders)

39.5% of cases

www.alternet.org/story/88515/the_startling_truth_about_doctors_and_diagnostic_errors

Study B
(Focused on
laboratory test
ordering mistakes)

11.5%

**(J Am Board Fam Med
27:268-274, 2014)**

Diagnostic Errors Associated with Office Visits and Initial In-patient Visits

Study C
(with the authors indicating that this is likely a significant underestimation)

5%
(BMJ Qual Saf 23:1023-1030, 2014)

Study D
(considers medical errors of all types – diagnostic errors would be about 25% of this total)

**6.6% Medical – 1.45%
Diagnostic error**
(J Med Econ 16:1367-1378, 2013)

Diagnostic Errors Associated with Office Visits and Initial In-patient Visits

This averages to 14.3% of the office and in-patient visits involving a diagnostic evaluation are associated with a diagnostic mistake

This averages to 1 in 7 outpatient/in-patient encounters requiring a diagnosis involves an error in diagnosis

How Many Medical Errors, Including Diagnostic Errors, Should You Expect to Experience Yourself?

Number of visits to a doctor (outpatient and inpatient):

Age 0-5 3/year = 15

Age 5-65 2/year = 120

Age 65-90 4/year = 100

325

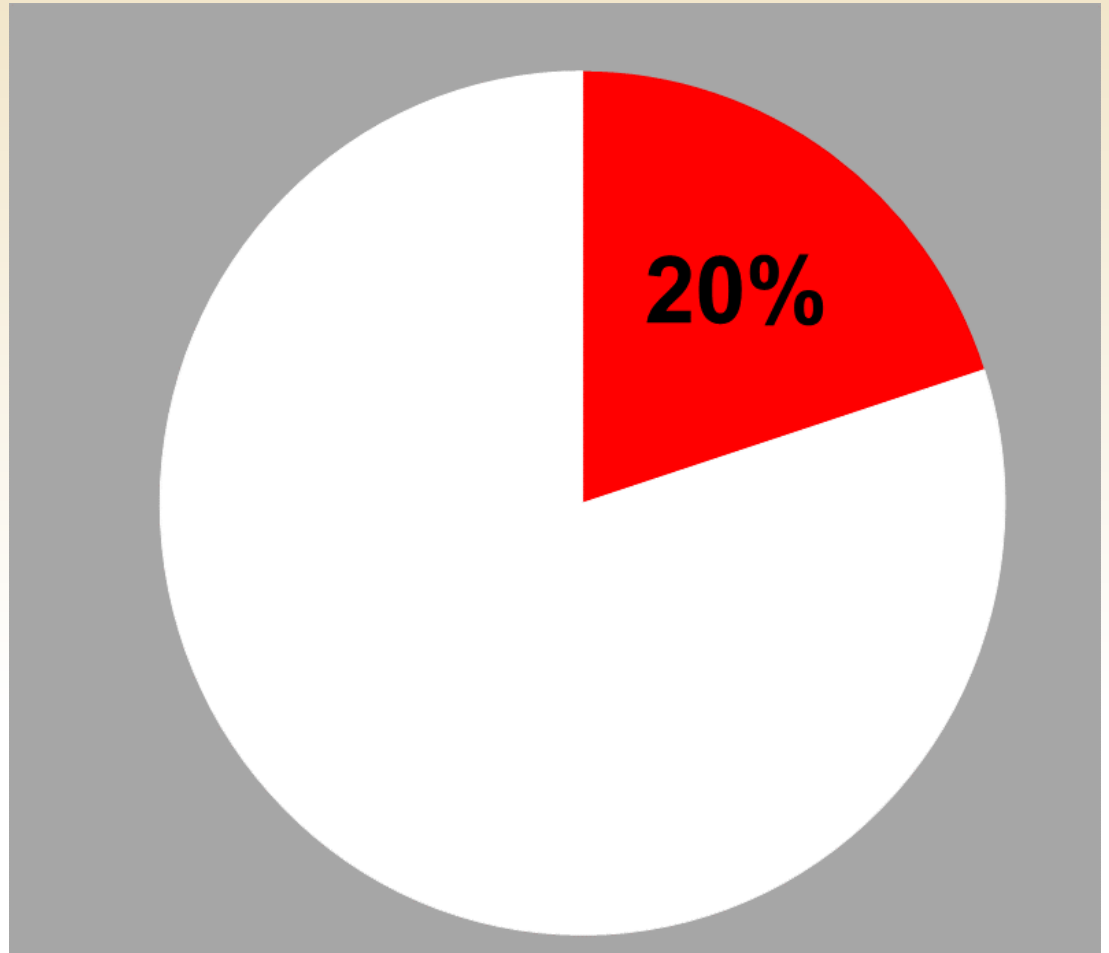
Assume only half of these are associated with possible
new diagnoses:

160 diagnostic visits

Assume error in one out of 10 visits (<1 out of 7):
16 errors in a lifetime FOR ONE PERSON

Percentage of Adult Americans Who Think They Have Experienced Diagnostic Errors

**Only 20%
or
one out of
five people**



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Perspectives

Patients Cannot Effectively Assess the Skill Level of Doctor

Bedside Manner

Skill Level

Perception

Polite and kind

Highly competent

“Good Doctor”

Polite and kind

Incompetent

“Good Doctor”

Dr. “HODAD”:
Hands of Death
and Destruction

Medical Errors

I Have Personally Experienced

SEVERE, DIAGNOSTIC: Major blow to the head, unconscious for 10 minutes; primary care physician took my blood pressure and sent me home with no observation period

MINOR, TREATMENT: Prescribed a bowel stimulant for an upper respirator tract infection

MODERATE, DIAGNOSTIC: Underwent an esophageal biopsy which was lost before it could be reviewed by pathology

Medical Errors

I Have Personally Experienced

MINOR, DIAGNOSTIC: Esophageal biopsy result received 13 days after completion of the biopsy

MODERATE, DIAGNOSTIC: CAT scan for pulmonary embolus (70 times the radiation of a chest x-ray) when I was not short of breath and only because I had been on an airplane

MODERATE, TREATMENT: Virtually no advice on cardiovascular protection using aspirin or fish oil

Medical Errors

I Have Personally Experienced

MODERATE, DIAGNOSTIC: Gum infection following dental implant of a molar with delay in recognition of the infection and loss of the implant

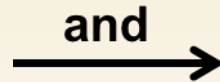
MODERATE, DIAGNOSTIC: Inadequate bowel preparation dose prior to lower G.I. evaluation making the evaluation for cancer in the large intestine impossible

There are 2 additional treatment errors not mentioned on these slides.

Number of Diagnostic Errors in One ICU Stay Can Be Many Because There Are Many Diagnoses to Be Made or Ruled Out in One Stay

Primary clinical problem is diagnosed

Change in primary problem must be monitored and appearance of new problems detected



Diagnosis of complications must be rapid and accurate for:

MI

Stroke

DVT/PE

CLABSI

UTI

VAP

Respiratory compromise

Goals for Improving Diagnosis and Reducing Diagnostic Error

- **Facilitate more effective teamwork in the diagnostic process among health care professionals, patients, and their families**
- **Enhance health care professional education and training in the diagnostic process**

Goals for Improving Diagnosis and Reducing Diagnostic Error

- **Ensure that health information technologies support patients and health care professionals in the diagnostic process**
- **Develop and deploy approaches to identify, learn from, and reduce diagnostic errors and near misses in clinical practice.**

Goals for Improving Diagnosis and Reducing Diagnostic Error

- **Establish a work system and culture that supports the diagnostic process and improvements in diagnostic performance**
- **Develop a reporting environment and medical liability system that facilitates improved diagnosis through learning from diagnostic errors and near misses**

Goals for Improving Diagnosis and Reducing Diagnostic Error

- **Design a payment and care delivery environment that supports the diagnostic process**
- **Provide dedicated funding for research on the diagnostic process and diagnostic errors**